TRACHEAL CATHETER AND PROSTHESIS AND METHOD OF RESPIRATORY SUPPORT OF A PATIENT

PRIORITY CLAIM

This patent application claims the benefit of priority under 35 U.S.C. § 119 to co-pending German Patent Application Serial No. 20/40963-001, filed August 11, 2003.

FIELD OF INVENTION

The present invention relates generally to respiratory systems directed and more particularly to specialized mechanisms for enhanced ventilation of a patient.

BACKGROUND OF THE INVENTION

In order that the body can take in oxygen and give off carbon dioxide, both components of the respiratory bronchial system must function – the lungs as a gas-exchanging organ and the respiratory pump as a ventilation organ that transports air into the lungs and back out again. The breathing center in the brain, central and peripheral nerves, the osseous thorax and the breathing musculature as well as free, stable respiratory paths are necessary for a correct functioning of the respiratory pump.

In certain diseases there is a constant overload on or exhaustion of the respiratory pump. A typical syndrome is pulmonary emphysema with flat-standing diaphragms without the ability to contract. In the case of pulmonary emphysema the respiratory paths are usually extremely slack and tend to collapse. As a consequence of the flattened, over-extended diaphragms the patient cannot inhale deep

enough. In addition, the patient cannot exhale sufficiently on account of the collapsing respiratory paths. This results in an insufficient respiration with an undersupply of oxygen and a rise of carbon dioxide in the blood, the so-called ventilatory insufficiency.

The treatment for inhalation difficulty often makes use of a breathing device. The so-called home respiration is an artificial respiration for supporting or completely relieving the respiratory pump.

The respiration can take place non-invasively via a tube and a nose mask or mouth mask that the patient can put on and take off as needed. However, this prevents the patient from breathing freely and speaking freely. In addition, a blocked tracheal cannula can be inserted into the trachea. This also has the consequence that the patient can no longer speak.

In the case of invasive respiration this usually occurs via a tracheostomy. This involves an opening placed in the trachea by an operation. A catheter about the diameter of a finger with a blocking balloon is inserted via the opening into the trachea and connected to a breathing apparatus. This makes a sufficiently deep respiration possible but prevents the patient from speaking. In addition to the respiration there is the transtracheal administration of oxygen via thinner catheters. US Patent Nos. 5,181,509 or 5,279,288 disclose corresponding embodiments. In this manner a highly dosed administration of oxygen is administered to the patient in a continuous stream with a permanently adjusted frequency. The flow of oxygen is regulated manually by a throttle device. However, simulation of the natural breathing process of a patient is not achieved because breathing is not deep enough. Also, the catheter end introduced into the trachea can result in irritations and a local traumatizing of the surrounding tissue in that it strikes against the trachea as a

consequence of the respiratory movement or in that the surrounding tissue is dried out by the jet stream.

Furthermore, so-called "Montgomery T-tubes" are known that are inserted into the trachea. The patient can obtain oxygen via the shank of the T-piece run to the outside. In addition, the patient can draw off secretions himself if needed. The patient can breathe freely and speak when the front shank is closed; however, respiration is not possible via the Montgomery T-tube since the introduced air escapes upward into the buccal cavity or the pharyngeal area. An additional limitation of the above-referenced therapies is the impaired mobility of the patient because of inadequate ventilation as well as the bulk of the apparatus.

Therefore, there is an existing need for a respiratory system that provides a more efficient method for supporting the respiration of a patient and of creating an apparatus to this end that can also be taken along by the patient and is reliable in its use. Moreover, the there is a need for a tracheal prosthesis and a catheter that make possible a respiratory support synchronized with the spontaneous respiration of the patient without adversely affecting the patient's ability to speak.

SUMMARY OF EXEMPLARY EMBODIMENTS

It is a principal objective of the present invention to provide an apparatus and method that improves the quality of life of patients that require respiratory support. In the furtherance of this and other objectives, the present inventor provides a respiratory system that provides a more efficient method of supporting the respiration of a patient by providing additional oxygen when needed.

I is an additional objective in accordance with the present invention to provide as system that is portable and reliable in its use.

Yet another objective in accordance with the present invention is to provide a tracheal prosthesis and a catheter that make possible a respiratory support synchronized with the spontaneous respiration of the patient without adversely affecting the patient's ability to speak.

Further objectives, features and advantages of the invention will be apparent from the following detailed description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE FIGURES

FIG. 1 shows the upper body of a patient carrying an apparatus in accordance with the invention for respiration support.

FIG. 2 shows a diagram with a view of the respiration flow of an emphysema patient with and without respiration support.

FIG. 3 shows a technically simplified view of a tracheal prosthesis in accordance with the invention.

FIG. 4 shows another embodiment of a tracheal prosthesis.

FIG. 5 shows, also in a scheme, an oxygen pump belonging to the apparatus of the invention showing the conduction of air and a control unit.

FIG. 6 shows the end section of a catheter in accordance with the invention.

FIG. 7 shows the catheter according to FIG. 6 inserted in a support body.

DETAILED DESCRIPTION OF AN EMBODIMENT

The present invention, in a preferred embodiment, provides an apparatus for supporting the respiration of a patient and to a tracheal prosthesis. According to the invention the spontaneous respiration of a patient is detected by sensors and at the end of an inhalation procedure an additional amount of oxygen is administered to the lungs

via a jet gas current. This improves the absorption of oxygen during inhalation. If required, the exhalation procedure of the patient can be arrested or slowed by a countercurrent in order to avoid a collapse of the respiration paths in this manner. This procedure is realized by an apparatus comprising an oxygen pump that can be connected to an oxygen source and comprising a tracheal prosthesis that can be connected via a catheter. The spontaneous respiration of the patient is detected by sensors connected to a control unit for activating the oxygen pump. The tracheal prosthesis comprises a tubular support body with a connection for the catheter and two of the sensors are associated with the support body. The tracheal prosthesis and the jet catheter that is integrated or can be introduced are dimensioned in such a manner that the patient can freely breath and speak without restriction.

Referring specifically to FIG 1, P designates a patient suffering from a pulmonary emphysema with an overloading and exhaustion of the respiratory pump. As a consequence, the patient can not inhale deeply enough. In addition, the exhalation process is hindered by slack and collapsing respiratory paths.

Such a respiration process with inhalation/inspiratory flow and exhalation (expiratory flow) without respiratory support is shown in FIG. 2 in the left half of the image. The curve for inhalation is designated by E1 and the curve for exhalation by A1.

In order to support and relieve the strain on the respiratory pump the patient's spontaneous respiration is detected by sensor and at the end of an inhalation process of the lungs an additional amount of oxygen is administered. This respiratory flow is illustrated in the right half of FIG. 2. The additional amount of oxygen increases the respiratory volume during inhalation according to curve E2 by the difference volume shown darkened in the upper curve and designated by E3.

The additional amount of oxygen can have a volume between 25 ml and 150 mm.

In addition, the exhalation process of the patient is braked by a countercurrent. As a consequence thereof, the respiratory flow shifts during exhalation along the curved designated by A2. This purposeful resistance acting opposite to the exhalation prevents a collapsing of the respiratory paths during exhalation. In this manner the exhalation volume is increased by the volume also shown darkened and designated by A3.

As a consequence, this method avoids an insufficient respiration with an undersupply of oxygen and an increase of carbon dioxide in the blood. Patient P is significantly less stressed and more mobile and in addition he perceives less or no shortage of air.

In order to carry out the respiration support of patient P, an apparatus is provided comprising oxygen pump 1 that can be connected to an oxygen source (see FIG. 5) and comprising tracheal prosthesis 2, 3 (see FIGS. 3, 4). According to FIG. 1 oxygen pump 1 is a component of a compact, mobile respiration device 4. Oxygen pump 1 and tracheal prosthesis 2, 3 are connected via catheter 5.

As FIGS. 3, 4 show, each tracheal prosthesis 2, 3 comprises tubular support body 6 with connection 7 for catheter 5. In order to detect the spontaneous respiration of patient P two sensors 8, 9 in the form of thermistors are associated with support body 6. One sensor 8 is fixed on inner wall 10 of support body 6 and the other sensor 9 is located on outer wall 11 of support body 6. Sensors 8, 9 communicate with control unit 12 for activating oxygen pump 2. Control unit 12 is schematically shown in FIG. 5 with its inputs and outputs. As already stated, sensors 8, 9 are thermistors, that is, temperature-dependent resistors. They are connected together in a bridge circuit in the apparatus so that a compensation of measured value differences

between inner sensor 8 and outer sensor takes place as a consequence of environmental influences.

FIG. 1 also shows that other respiration sensors 13, 14 are provided. They are also sensors for detecting the spontaneous respiration of patient P. An exact image of the respiration process of patient P can be obtained by adjusting the measured values received via sensors 8, 9 and 13, 14. In addition, the safety against false measurements or the failure of one of sensors 8, 9 and/or 13, 14 is increased.

In tracheal prosthesis 2 according to FIG. 3 the jet catheter 5 can be inserted via connection 7 into support body 6. End 15 of jet catheter 5 located in support body 6 is guided or deflected approximately parallel to its longitudinal axis L. The data lines from sensors 8, 9 to control unit 12 are designated with 16, 17 running inside catheter 5. On the discharge side the end 15 of jet catheter 5 is designed as jet nozzle 25. This can take place by reducing the cross section of the catheter. This increases the speed of the oxygen current at the discharge from catheter 5 and it is conducted in the direction of the bronchial tract. The diameter of support body 6 is dimensioned with a sufficiently free lumen in such a manner that patient P can freely breathe and speak even with integrated catheter 5.

Separate coupling 18 is provided on connection 7 in tracheal prosthesis 3 according to FIG. 4 via which catheter 5 is connected to tracheal prosthesis 3. In this instance fixed longitudinal section 19 aligned parallel to longitudinal axis L is provided as catheter end in support body 6 and the oxygen current is conducted via jet nozzle 26 in the direction of the bronchial tract.

Oxygen pump 1 is schematically shown in FIG. 5. It is a piston pump with double-acting piston 20 arranged in cylinder 27. The apparatus comprises four valves V1 to V4. The supply of oxygen takes

place from an external oxygen reservoir via connection 21. The switching states of valves V1 to V4 and the supply lines and removal lines are designated by letters a to g.

Oxygen pump 1 functions in the apparatus during the support of respiration as follows: When valve V1 is open from c to a (b to c closed) and valve V2 open from b to 3 (e to d closed), piston 20 moves to the left in the plane of the figure and the oxygen flows via outlet 22 and jet catheter 5 to patient P. The additional amount of oxygen E3 is administered during the inhalation process of patient P.

When valve V1 is open from b to c (c to a closed) and valve V2 is open from e to d (b to e closed), piston 20 moves to the right in the plane of the figure in the flow of oxygen takes place in the direction of valve V3. Valve V3 is connected to the ambient air via outlet 23. In the instance in which valve V3 is open from d to g the oxygen flows off without expiration brake. That means that the exhalation process is not braked by a countercurrent.

If valve V3 is closed from d to g and open from d to f the oxygen flows via access path 24 in the direction of outlet 22 and catheter 5 in order to be administered to patient P during the exhalation process and in order to break the respiratory flow. The countercurrent prevents a collapsing of the respiratory paths and keeps them open. This makes a deeper exhalation possible.

Furthermore, valve V4 is located in access path 24 of the apparatus, via which the flowthrough (f to a) can be variably adjusted. This can advantageously be a proportional valve with pulse-width modulation.

FIG. 6 shows catheter 28 with long, flexible tube 29 and end 31 on the discharge side bent in curvature 30. Two sensors 32, 33 for detecting the spontaneous respiration of patient P are fastened on the end. Sensors 32, 33 are preferably thermistors. Data lines are not

shown in the drawing for the sake of simplicity. They run through catheter 28 and the catheter wall. 34 designates a stop.

It can also be seen that end 31 of catheter 28 is provided with jet nozzle 35. The cross section of the flow is reduced relative to the cross section of the catheter in jet nozzle 35 so that the discharge rate of the supplied oxygen is increased.

Catheter 28 can be introduced into support body 36, as FIG. 7 shows. Support body 35 is located in the trachea of patient P. The connection to the outside is established via connection 37. Support body 36 can be a traditional Montgomery T-stent.

The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative, and not restrictive. The scope of the invention is, therefore, indicated by the appended claims, rather than by the foregoing description. All changes, which come within the meaning and range of equivalency of the claims, are to be embraced within their scope.